Mr. Chairman, Members of the Subcommittee, my name is William B. Schultz. I am the Deputy Commissioner for Policy at the Food and Drug Administration (FDA). Appearing with me today are Ms. Mary Pendergast, the Deputy Commissioner and Senior Advisor to the Commissioner; Dr. Bruce Burlington, the Director of the Center for Devices and Radiological Health; Mr. Joseph Levitt, the Deputy Director of the Center for Devices and Radiological Health; and Ms. Margaret Jane Porter, our Chief Counsel. We are here today to discuss FDA's regulation of products that can be used in the home and in other nonprofessional settings (over-the-counter (OTC)) to test for drugs of abuse.

Let me start by saying that the Agency has listened to the concerns you expressed regarding the regulation of drugs of abuse test systems. We have developed a common sense proposal that encompasses a level of regulation that takes into account the public health concerns associated with these test systems, but imposes the minimal level of regulation necessary to address those concerns. As outlined below, the approach we are proposing will be minimally disruptive for two reasons. First, it will eliminate the premarket approval or clearance requirements for drugs of abuse test systems that satisfy minimal criteria. Second, it provides for a long transition period to allow

companies time to conform to the policy. The approach that I will describe will be the subject of notice-and-comment rulemaking and a public hearing before the Agency adopts a final policy on the regulation of OTC drugs of abuse test systems.

BACKGROUND

Drugs of abuse test systems typically consist of a collection cup or other container for collecting a specimen, directions for use, packaging for storage or mailing, access to a laboratory testing service using an appropriate test, and access to test results and counseling. The consumer collects a specimen (such as urine) from the body and mails it to a laboratory, which performs the actual testing for the drugs or metabolites. The specimen usually is identified by a code number, which maintains confidentiality and protects against mix-ups. The test results are communicated back to the consumer. The consumer may or may not be asked to pay extra for confirmatory testing on those samples that screen positive.

On September 26, 1996, this Subcommittee held a hearing on home drugs of abuse test systems. Members of this Subcommittee raised several concerns about the Agency's regulation of home drugs of abuse test systems. First, you pointed to several internal Agency memoranda that suggested that some Agency employees held

the view that concerns relating to the parent-child relationship or family discord may be relevant in making approval decisions on such test systems. FDA's evaluation of these home test systems must focus on scientific questions about whether the test is properly labeled and gives accurate results as well as any concerns about personal and public health. Concerns about the effect of a product on the parent-child relationship or family discord have no place in the Agency's determination as to whether that product meets the requirements of the Federal Food, Drug, and Cosmetic Act.

Second, members of the Subcommittee maintained that the Agency's categorization of these test systems as class III medical devices was unnecessarily stringent and that there are benefits to making these products available to parents. You also pointed out the inconsistency between the Agency's regulation of drugs of abuse test systems for use in the home setting and its policy of not actively regulating drugs of abuse test systems used in the workplace, insurance, sports, and law enforcement settings. After considering these issues, the Agency agrees that both of these arguments have merit.

Following the September 1996 hearing, we at FDA reevaluated our policies to determine the appropriate level of regulation for home drugs of abuse test systems. In fact, on October 3, 1996,

we established an interim policy in which we agreed not to take regulatory action against persons distributing home drugs of abuse test systems so long as: (1) the laboratory conducting the testing used an FDA-cleared test, (2) the testing laboratory met the Substance Abuse and Mental Health Services Administration (SAMHSA) or equivalent standards for performing such testing, and (3) the product had accurate labeling. A copy of the Agency's interim policy was provided to the Subcommittee and is appended to this testimony.

FDA AND THE DEPARTMENT OF HEALTH AND HUMAN SERVICES SUPPORT THE USE OF ACCURATE AND RELIABLE DRUGS OF ABUSE TESTING

Before discussing the Agency's reevaluation of its policy on home drugs of abuse test systems, let me say that FDA does support the marketing of these test systems, provided they are accurate and reliable. In fact, on January 21, 1997, we approved Dr. Brown's Home Drug Testing System, which meets all of the criteria under the Agency's original policy. Dr. Brown's test system, which was cleared through the PMA process, uses a drug screening urine test that has been cleared previously by FDA and incorporates confirmatory testing. Directions for use and for obtaining and interpreting results are included in the labeling to make it easier for parents to understand the test results. In addition, health representatives are available to convey the test results

and provide information about the meaning of the test results and further medical referral if parents request additional help.

The Department of Health and Human Services supports accurate and reliable drugs of abuse testing. The Substance Abuse and Mental Health Services Administration (SAMHSA) certifies drug testing laboratories engaged in urine testing for Federal agencies, identifies the tests that can be used, and trains physicians on the interpretation of drug testing results. Recognizing that the usefulness of testing for drugs of abuse resides in its accuracy and reliability, the National Institute on Drug Abuse (NIDA) sponsors a national program of research on basic methodology and clinical applicability of drug testing methods. In FY 1996, NIDA supported research at its own Intramural Research Laboratories, as well as six extramural research projects, to advance and refine its knowledge of the scientific basis and application of drugs of abuse testing. These projects encompass studies of the science of hair, saliva, and sweat testing and directly address scientific questions related to sensitivity, specificity, reproducibility, and reliability of the test methods, their relative strengths and weaknesses, and their applications -- the type of data that can form a basis for informed regulatory and approval decisions.

THE AGENCY'S REEVALUATION OF ITS POLICY

In reevaluating our policy on home drugs of abuse test systems, the Agency reached a number of conclusions. Our first principle is that these test systems must be accurate and reliable. Because there are more than 200 FDA-cleared urine tests for detecting drugs of abuse and hundreds of Federally-certified laboratories capable of conducting this testing, accurate and reliable testing is available now.

Second, because there is value in having drugs of abuse test systems available for use in the home setting, we believe that it should be easier to get them onto the market for such use. We think we can accomplish this and still ensure that consumers get the right answer from these test systems.

Third, with respect to the inconsistency in our regulation of drugs of abuse test systems for use in the home setting and such systems used in the workplace, insurance, and sports settings, we have concluded that the same concerns about getting an accurate and reliable answer apply equally in all of those settings. Thus, we have concluded that FDA should apply the same rules to drugs of abuse test systems used in all nonprofessional settings. On this point, however, let me assure the Subcommittee that, in developing a regulatory approach, we have been sensitive to any potential disruption to the existing marketplace. We are seeking to ensure the reliability and accuracy of OTC drugs of abuse test

systems, while minimizing the disruption to the marketplace, by proposing reasonable criteria and a transition period for conformance with the criteria.

Fourth, we concluded that FDA should continue to exercise its enforcement discretion not to regulate testing for drugs of abuse in the law enforcement setting because there are other protections to assure sample integrity and test accuracy that are not available in the home, workplace, insurance, and sports settings. The additional protections include the use of rules of evidence in judicial proceedings and the representation of the accused (i.e., the person being tested) through the judicial process.

Finally, in reevaluating our policy on OTC drugs of abuse test systems, we determined that it is important to give the marketplace time to adjust to any changes in our regulatory approach. Therefore, the Agency is proposing to provide an adequate transition period for implementing its proposed policy. We recognize the importance of empowering parents to address the abuse of drugs by their children with reliable, accurate, and reasonably affordable detection capability. We must move aggressively, however, to assure parents of the reliability of such products for home use.

DA’S PROPOSED POLICY

FDA believes that three basic criteria are needed to assure that drugs of abuse test systems are safe and reliable for use in a nonprofessional setting. If these criteria are met, FDA proposes to allow companies to market OTC drugs of abuse test systems without first obtaining premarket approval or clearance. The three criteria are as follows.

First, the laboratory test(s) must have been recognized by FDA as accurate and reliable for laboratory use. This will ensure that drugs of abuse test systems that are sold to consumers will be accurate and reliable. It would allow FDA to utilize the expertise of another Federal agency (e.g., SAMHSA) when that agency reaches a formal determination regarding the suitability of a particular test system.

Since FDA already has cleared more than 200 laboratory urine tests to detect drugs of abuse, companies would have a relatively easy route to marketing OTC drugs of abuse urine test systems. Once this new policy is implemented, however, companies seeking to market a system that uses a hair test or any other test that has not been recognized by FDA would need to establish the validity of the test with FDA prior to marketing. FDA’s proposed policy implementation would allow ample time for companies to do

this.

The second criterion for ensuring that drugs of abuse test systems are safe and reliable for use in a nonprofessional setting is that the laboratory performing the underlying test(s) must be able to reliably perform the necessary initial and confirmatory tests. This will ensure that testing is performed by individuals with appropriate levels of training, knowledge, and proficiency; that confirmatory testing is systematically performed on presumptively positive samples prior to issuance of the test results; and that assistance with interpretation of the test results and follow-up counseling is available to the consumer by a trained health professional, if requested.

We do not believe this criterion will create a barrier to marketing. There are 75 laboratories certified by SAMHSA that would meet the requirements set forth in the second criterion. In addition, there are thousands of laboratories certified in the area of toxicology testing under the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). We believe that many of these CLIA-certified laboratories, particularly the high complexity laboratories, would have the appropriate types of controls.

The third criterion to ensure that drugs of abuse test systems

are safe and reliable for use in a nonprofessional setting is that samples are adequately identified to avoid mix-ups and that the system is accurately labeled so that consumers can readily use it. This will ensure that the test system is accompanied by adequate directions that enable the lay person to:
(a) understand the purpose of the test -- i.e., what drugs can and cannot be identified in the specimen; (b) understand the detection period; and (c) properly collect the test specimen and mail it to the laboratory. The labeling also would provide information regarding interpretation of test results (e.g., false positives and false negatives) and how the consumer can contact a qualified health professional for assistance in that interpretation. FDA plans to develop guidance on issues such as how to label the test system so that the consumer can understand the test results and to ensure that the specimen and the container remain properly identified and intact during mailing to the laboratory. The guidance also will address methods for providing consumers with adequate professional assistance in interpreting/understanding test results and providing counseling referrals, if needed. This third criterion will be easy to meet.

If the above three basic criteria are met, FDA proposes to allow companies to market OTC drugs of abuse test systems without first obtaining premarket approval or clearance, as was previously required. In other words, companies would not need to file a

premarket approval application (PMA) or premarket notification (510(k)) before marketing these test systems. Drugs of abuse test systems for use in a nonprofessional setting, therefore, would be subject to very limited regulation.

Under FDA's proposal, FDA would consistently regulate: (a) home drugs of abuse test systems; and (b) drugs of abuse test systems that are used in the insurance, workplace, and sports settings. If the tests currently being marketed are reliable, the impact on testing provided in these latter venues is expected to be small for two reasons. First, FDA is proposing that the products be exempt from the premarket approval or clearance requirements of sections 515 and 510(k) (provided the conditions/criteria for assuring their accuracy and reliability are met); and, second, if a manufacturer/distributor wants to market a test system for use in the insurance, workplace, or sports setting that does not rely on use of a laboratory test that has been recognized by FDA, the transition period prior to the effective date of the final rule will provide sufficient time to obtain FDA recognition for any test that is accurate and reliable

IMPLEMENTATION OF FDA'S PROPOSAL

FDA intends to implement its proposed policy through notice-and-comment rulemaking. As part of the rulemaking process, following

publication of the proposed rule, FDA will hold a public hearing to solicit additional public comment on its proposal. The Agency will carefully consider the public comments we receive and welcomes comments from members of this Subcommittee. FDA will propose that the effective date for the final rule provide a reasonable transition period so that companies that need to submit their test to FDA for recognition will have sufficient time to collect the requisite data. The Agency expects to complete the notice and comment process and to have this new policy fully in place in approximately two years.

In the meantime, the Agency will not actively regulate drugs of abuse test systems used in the workplace, insurance, or sports settings. Because the Agency has not been actively regulating test systems used in these settings, we believe it is appropriate to provide notice and comment before changing its practice. The Agency also will not regulate the drugs of abuse hair test system that was the subject of the court settlement or OTC products that are substantially similar to that system. The Agency's October 3, 1996 interim policy will apply to all other test systems for use in the home setting. It will permit the marketing of home test systems that use FDA-cleared urine tests for drugs of abuse and home test systems that use any other FDA-cleared tests for drugs of abuse. Because there are more than 200 FDA-cleared tests for urine -- i.e., the technology is there

-- parents will have the benefit of a cleared/accurate test during the rulemaking. The Agency also intends to make every effort to inform the public of the importance of following prescribed procedures to assure the test results are accurate and reliable.[1]

CONCLUSION

As a consumer protection agency, FDA's most important role in overseeing the regulation of diagnostic tests is to assure that they provide the right answers. This consideration is critical for drugs of abuse test systems sold to consumers. FDA believes that its proposed regulatory approach would accomplish this goal because it focuses on the accuracy and reliability of the underlying test(s). At the same time, FDA's proposal would

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[1] According to Ms. Sunny Cloud's September 26, 1996 Congressional testimony, the urine testing portion of the Parent's Alert product is conducted by a SAMHSA-certified laboratory. SAMHSA-certified laboratories use only FDA-cleared urine tests. Therefore, the urine test system component of Ms. Cloud's product should meet the requirements set forth in our interim policy.

We understand that a point of care saliva test also is included in the Parent's Alert product. The Agency's policy on OTC test systems for drugs of abuse does not apply to point of care tests. Point of care tests have always required FDA approval prior to marketing. FDA does not plan to change that policy. However, in an October 3, 1996 letter to Ms. Cloud, the Agency committed to not taking regulatory action against the Parent's Alert product until a policy on home test systems was in place. The Agency will honor that commitment and not take action against the point of care test in the Parent's Alert product until its proposed policy is in place.

significantly ease the requirements that must be met in order to sell these products. Moreover, because it would provide an adequate transition period, there should be no interruption of the availability of test systems for use in nonprofessional settings.

STATEMENT

BY

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FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON COMMERCE

U.S. HOUSE OF REPRESENTATIVES

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RELEASE ONLY UPON DELIVERY

PARENTS' ACCESS TO TESTS FOR DRUGS OF ABUSE

PURPOSE

This guidance describes how FDA will exercise its enforcement discretion for home test collection systems for drugs of abuse. It is intended to provide for the availability of home test collection systems sold directly to parents for use in the home setting, while FDA develops a final policy regarding the appropriate level of regulation of these products. FDA intends to exercise its enforcement discretion and not take any regulatory action against persons distributing such products during this interim period, so long as the criteria listed below are met. Once a final policy is in place, manufacturers and distributors will be expected to be in compliance, or come into compliance, with that final policy.

SCOPE

This guidance covers home test collection systems for drugs of abuse that are intended to be sold directly to parents for use in the home setting. The testing procedures for these products require that a specimen from the body (e.g., urine) be collected at home and mailed to a designated laboratory for testing. Test results are then communicated back to the parent.

CRITERIA

FDA intends to exercise its enforcement discretion during this interim period with respect to home test collection systems and their components that meet all of the following criteria:

1. The tests(s) to be used by the laboratory have been cleared for marketing by FDA for identifying drugs of abuse in a laboratory setting;

2. The laboratory performing the test(s) has been certified by SAMHSA as having the necessary capability to reliably perform such test(s) or meets equivalent standards; and

3. The product ensures that samples are adequately identified to avoid mix-ups, and is accurately labeled so that parents can readily use it.

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